

TITLE 905 ALCOHOL AND TOBACCO COMMISSION

Proposed Rule LSA Document #15-290

DIGEST

Adds 905 IAC 1-48 concerning the manufacture, distribution, and sale of e-liquid. Effective upon passage.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

905 IAC 1-48

SECTION 1. 905 IAC 1-48 IS ADDED TO READ AS FOLLOWS:

Rule 48. Regulations relating to manufacture, distribution, and sale of e-liquids

905 IAC 1-48-1 Purpose and application

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 1. (a) The purpose of this rule is, in the absence of federal regulations, to protect public health and safety by:

- (1)** ensuring the safety and security of e-liquid manufactured for sale in Indiana;
- (2)** ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and
- (3)** ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.

(b) This rule applies to the commercial manufacturing, bottling, selling, bartering, or importing of e-liquid products in Indiana and the sale, possession, and use of e-liquid products in Indiana.

905 IAC 1-48-2 Sale to minors prohibited

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 2. Any e-liquid or nicotine product, including nonrefillable sealed cartridge electronic cigarettes, sold for use in Indiana may not be sold to anyone less than eighteen (18) years of age.

905 IAC 1-48-3 Definitions

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 3. (a) The definitions in IC 7.1-7-2 and this SECTION apply throughout this rule.

(b) "Commission" or "ATC" means the Indiana Alcohol and Tobacco Commission

(c) "Packaging" means the process by which e-liquid is bottled in a tamper evident package with a child resistant cap and labeled in compliance with IC 7.1-7. The term does not include the process of preparing to ship or distribute already manufactured and packaged e-liquid.

905 IAC 1-48-4 Manufacturer application

Authority:

Affected:

Sec. 4. (a) The application must include the following:

- (1) The initial application requirements listed in IC 7.1-7-4-1(d).**
- (2) Full legal name, address, date of birth, Social Security number, and primary telephone contact number for each owner.**
- (3) Full legal name, telephone number, date of birth, Social Security number, title, and address of the facility managers responsible for the manufacturing facility.**
- (4) Floor plans, marked as confidential under IC 7.1-7-3-2, of the manufacturing facility that show the layout of the entire manufacturing facility including the following:**
 - (A) The clean room.**
 - (B) The storage room where sample bottles are stored as required by IC 7.1-7-4-6.**
 - (C) All entrances, exits, and interior doors.**
 - (D) All areas open to the public, including areas used for sales or distribution of e-liquids.**
- (5) An executed security agreement showing compliance with the requirements of IC 7.1-7-4-1(d)(3) and IC 7.1-7-4-6(b)(10) through IC 7.1-7-4-6(b)(15). A security agreement will be treated as confidential and only be released pursuant to a court order.**
- (6) A verified statement from the security firm that includes the following:**
 - (A) Name of at least one (1) employee of the security firm who is accredited or certified by the Door and Hardware Institute as an architectural hardware consultant.**
 - (B) Name of at least one (1) employee of the security firm who is accredited or certified as a certified rolling steel fire door technician by the International Door Association or the Institute of Door Dealer Education and Accreditation.**
 - (C) Name of the employee of the security firm who is a locksmith.**
- (7) Statement that no individuals, corporations, limited liability companies, limited liability partnerships, partnerships or stock owners, members, or partners of such entities with an interest, either directly or indirectly, in the security company have any interest, either directly or indirectly, in any e-liquid manufacturer, distributor, or retailer.**
- (8) A verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in IC 7.1-7-5-1(a).**
- (9) An addendum, marked as confidential, that provides a product listing that complies with SECTION 8 of this rule.**
- (10) A verified statement that the facility will comply with manufacturing processes required by IC 7.1-7 and this rule.**
- (11) A verified statement that equipment used is easily cleanable as defined in 410 IAC 7-24-27(a).**
- (12) Written consent to allow a law enforcement officer to conduct a state or national criminal history background check on any person listed on the application.**
- (13) Written consent allowing the commission, or its duly appointed agents, after a permit is issued to the applicant, to enter during normal business hours the premises where the e-liquid is manufactured to conduct physical inspections, sample the product to ensure the e-liquid meets the requirements for e-liquid set forth in this article, and perform an audit.**
- (14) Any other information as deemed appropriate by the commission to complete review of the application.**

(b) Failure to make a timely and accurate notification required by IC 7.1-7-4-5 may result in the denial or revocation of the application.

905 IAC 1-48-5 Time allotted for review and action by the commission

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 5 (a) The commission shall complete its review and take final action upon the application within sixty (60) days after receiving all information and documentation required by IC 7.1-7 and this rule, including, but not limited to the following:

- (1) The completed application form.**
- (2) The certification by the security firm that the manufacturing facility is in compliance with the requirements of IC 7.1-7-4-1(d)(3) and IC 7.1-7-4-6(b)(10) through IC 7.1-7-4-6(b)(15).**
- (3) A fully compliant service security agreement is executed with the final copy submitted to commission.**
- (4) Product listing that complies with SECTION 8 of this rule.**
- (5) Payment of the application fee.**
- (6) Floor plan.**
- (7) Any other outstanding matters required by the commission are satisfied.**

(b) For an out of state or out of country manufacturing facility that the commission is unable to physically inspect, arrangements may be made for an independent provider approved by the commission to perform such inspection. The out of state approved inspection provider will be required to submit the results of the inspection directly to the commission via first class mail.

905 IAC 1-48-6 Renewals

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 6. (a) Applications for renewals of existing permits must be submitted to the commission on an application form prescribed by the commission at least sixty (60) days before the expiration date of the existing permit and must include the following:

- (1) The renewal application requirements listed in IC 7.1-7-4-2(b).**
- (2) The full legal name, address, and primary telephone contact number for each owner.**
- (3) The full legal name, address, and primary telephone contact number for each facility manager responsible for the manufacturing facility.**
- (4) Evidence that the security firm complies with the requirements of IC 7.1-7 by either:**
 - (A) a verified statement by the security company that the information provided in the initial application or most recent renewal applicant continues to be correct; or**
 - (B) a verified statement as required by SECTION 4(a)(7) of this rule that includes any changes to the security company.**
- (5) A verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in IC 7.1-7-5-1(a).**
- (6) A verified statement that the manufacturing process used by the applicant complies with the requirements of IC 7.1 and this rule.**
- (7) Written consent allowing law enforcement to conduct a state or national criminal history background check on any person listed on the application.**
- (8) Any other information as deemed appropriate by the commission that is relevant to the renewal application.**

(b) Failure to make a timely and accurate notification required by IC 7.1-7-4-5 may result in the denial of the application.

905 IAC 1-48-7 Transfer of permits

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 7. (a) As used in this SECTION, “sample” means the three (3) ten (10) milliliter sample bottles from each production batch of more than two (2) liters required to be stored or maintained by IC 7.1-7-4-6(b)(15).

(b) An e-liquid manufacturer transferring the location of the permit shall maintain the samples in a secure, limited access area during the transfer of location by complying with the following:

- (1) The e-liquid manufacturer must notify the commission of the anticipated date the samples will be removed from the original location and the anticipated date the samples will be moved into the new location.
- (2) Samples may only be removed from the secure, limited access area with recorded video surveillance at the original location by designated employees of the e-liquid manufacturer.
- (3) Samples removed from the secure, limited access area with recorded video surveillance at the original location must be placed immediately in a secure, limited access container or vehicle for transporting to the new permit location.
- (4) Video surveillance may not be removed or disconnected from the secure, limited access area until all samples are removed to the secure, limited access container or vehicle.
- (5) The secure, limited access area for the storage of samples at the new location must have operational video surveillance before samples may be placed in the area.
- (6) The e-liquid manufacturer must notify the commission of the completion of the transfer within five (5) days after the completion of the relocation of the samples and equipment.
- (7) The e-liquid manufacturer must maintain a list of employees who had access to the samples during the transfer for a period of three (3) years.

905 IAC 1-48-8 Product listing

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 8. (a) The manufacturer shall provide a product listing to the commission at the time of the initial application for all e-liquid products manufactured in production batches of more than two (2) liters.

(b) The product listing shall include:

- (1) the product name;
- (2) for each product, the percentage of nicotine; and
- (3) the original date of manufacture of each product.

(c) The manufacturer shall notify the commission within thirty (30) days of the following:

- (1) The manufacture of a new e-liquid product manufactured in production batches of more than two (2) liters and the original date of manufacture.
- (2) The manufacture of an existing e-liquid product under a new or amended product name and the original date of manufacture under the new or amended product name.
- (3) The discontinuation and final manufacture date of an e-liquid product.

(4) The final date of manufacture of a discontinued product.

(d) The manufacturer shall maintain a record of each ingredient used in a production batch for three (3) years that includes the following information for each ingredient:

- (1) The ingredient, as listed in IC 7.1-7-5-1.
- (2) The manufacturer of each ingredient.
- (3) The batch from the manufacturer of each ingredient, if applicable.

The manufacturer shall provide the ingredient information for a production batch to the commission upon request.

905 IAC 1-48-9 E-liquid manufacturing

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 9. In order to comply with IC 7.1 relating to e-liquid manufacturing, the manufacturing facility must demonstrate compliance with the following:

- (1) The manufacturing requirements listed in IC 7.1-7-4-6.
- (2) E-liquid containers must be labeled.
- (3) Labels on e-liquid containers must identify all active ingredients, including percentage of nicotine.
- (4) Labels on e-liquid containers must include a means for the commission to obtain the manufacturing date either through a scannable code or printed on the label.
- (5) The video recordings required by IC 7.1-7-4-6 (b)(13) must be retained for at least thirty (20) days and are subject to commission audit for quality, purity, and compliance reviews.
- (6) An e-liquid container label or tamper resistant packaging may include a "best if used by" date.
- (7) A production log must be maintained listing the following:
 - (A) Date and time the e-liquid was produced.
 - (B) The name of the product manufactured.
 - (C) The amount of the product produced in liters.
 - (D) The code and batch number.
 - (E) Any person responsible for the mixing and bottling.

905 IAC 1-48-10 Random samples

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 10. (a) The commission may require an e-liquid manufacturer to have up to three (3) different products tested annually by one (1) of three (3) independent laboratories approved by the commission for safety, quality, and purity purposes.

(b) The commission will select up to the three (3) products to be tested pursuant to subsection (a) from the product listing provided to the commission under SECTION 8 of this rule.

(c) Failure by the e-liquid manufacturer to submit or pay the costs of a product testing required by subsection (a) will result in disciplinary action by the commission that may include fines, suspension, and revocation of the permit.

(d) The commission may require the laboratory to test for any of the following:

- (1) Nicotine.
- (2) Ingredients listed on the label.
- (3) Contaminants.
- (4) Illegal drugs.

(e) At the discretion of the commission, products that test positive for ingredients other than those listed on the label or on the ingredient list maintained by the e-liquid manufacturer under SECTION 8 of this rule may be subject to retesting at the cost of the e-liquid manufacturer.

905 IAC 1-48-11 Permit violations

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 11. Permit violations proceedings for e-liquid manufacturing permits shall be conducted pursuant to 905 IAC 1-37-1.

905 IAC 1-48-12 Procedure on denial

Authority: IC 7.1-2-3-7; IC 7.1-7-3-3

Affected: IC 7.1-7

Sec. 12. (a) If an initial or renewal application for an e-liquid manufacturing permit is denied by the commission, the commission shall give written notice of the action to the applicant.

(b) Upon receipt of notice of the commission's action, the applicant shall have fifteen (15) days to file:

- (1) A petition for administrative appeal; and
- (2) A brief objecting to the commission's action.

(c) The brief shall state any basis on which the applicant believes the application was denied in error.

(d) The commission shall provide for one (1) automatic extension of the fifteen (15) day period at the request of the applicant if made within the original fifteen (15) days.

(e) Failure of the applicant to file objections within the fifteen (15) day period shall constitute a waiver of any administrative appeal from the commission's action.

(f) At the discretion of the commission, a hearing may be conducted by the full commission, any individual member of the commission, or a duly authorized agent of the commission.

(g) The commission may conduct a prehearing conference. The hearing judge for the prehearing conference shall set the time and place of the conference and give reasonable notice to the applicant.

(h) The hearing officer shall set the time and place of the hearing on the denial and give reasonable notice to the applicant. At the hearing, the applicant may present evidence by presenting testimony, under oath or affirmation, documentary evidence, or written evidence.

(i) If the decision by the commission is ultimately appealed by the applicant, the hearing officer may consider any evidence presented in the original investigation, the commission hearing, or at the appeal hearing.

(j) If the appeal is based on the denial of an application for renewal of an existing license, the applicant may request an extension of the life of the license to allow him or her to continue operating pending the appeal procedure.

(k) Following the hearing, the hearing officer shall issue proposed findings of fact, conclusions of law, and order to the commission for its final approval.

(l) Such proposed findings of fact, conclusions of law, and final order shall be served on the applicant for the applicant's written objection, which is due to the commission within fifteen (15) days of the receipt of the proposed findings of fact, conclusions of law, and final order by the applicant.

(m) At the conclusion of the time for receipt of written objections, the commission shall approve, deny, or modify the proposed findings of fact, conclusions of law, and final order.

(n) In the case of denial of an application, the commission shall inform the applicant that its decision may be subject to judicial review.